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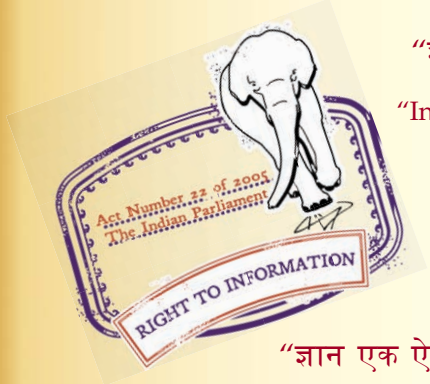
IS 11400 (1985): Hypodermic Syringes, Interchangeable Type for General Purposes [MHD 12: Hospital Equipment]



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IS : 11400 - 1985
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Indian Standard

SPECIFICATION FOR HYPODERMIC SYRINGES, INTERCHANGEABLE TYPE FOR GENERAL PURPOSES

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INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

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July 1986

IS : 11400 - 1985
(Superseding IS : 3238 - 1965)

Indian Standard

SPECIFICATION FOR HYPODERMIC SYRINGES, INTERCHANGEABLE TYPE FOR GENERAL PURPOSES

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Indian Standard

SPECIFICATION FOR HYPODERMIC SYRINGES, INTERCHANGEABLE TYPE FOR GENERAL PURPOSES

0. FOREWORD

0.1 This Indian Standard was adoptedby the Indian Standards Institution on 31 August 1985, after the draft finalized by the Medical Glass Instruments and Appliances Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.

0.2 An Indian Standard (IS :3238*) on the subject was first published in 1965. At that time, it had covered only the dimensions of interchangeable type hypodermic syringes and for other requirements, it was made complementary to IS :3235-1980† and IS : 3236 -1980‡. However, on account of certain difficulties and ambiguities observed during the course of its implementation, it has been considered expedient to cover the complete requirements for interchangeable type hypodermic syringes under one standard. The present standard, which is based on this consideration, is expected to help in the effective implementation of this standard.

0.3 The interchangeability between the syringes and the needles and between the barrels and the pistons of the syringes is an important aspect from the point of view of hospitals where selective assembly becomes somewhat difficult due to the mass sterilization of instruments. Interchangeability between the needles and syringes is assured due to adoption of Luer type of fittings for the conical tip of the syringe and hub of the needle (see IS :3234-1979§). The barrels and the pistons are made interchangeable by manufacturing them and testing them to high degree of accuracy to prescribed dimensions.

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*Dimension of hypodermic syringes, interchangeable type.

†General requirements for syringes for medical use (first *revision*).

‡Specification for hypodermic syringes for general purposes (first *revision*).

§Specification for conical fitting for hypodermic syringes, needles and other medical equipment, Luer type (*first revision*).

0.4 This standard is expected to ensure the interchangeability between the barrel acd the piston of all-glass syringes of same size made by different manufacturers.

0.5 This standard also incorporates the requirements for 30 ml and 100 ml syringes, which were not covered by the earlier standard (IS : 3238*).

0.6 The general requirements for hypodermic syringes for medical use are covered in IS : 3235-1980† which forms a necessary adjunct to this standard.

0.7 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960‡. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard covers requirements for interchangeable type, general purpose, all-glass, hypodermic syringes for medical use.

1.2 Unless otherwise stated in this standard, the provisions covered in IS : 3235-1980† shall apply.

2. TERMINOLOGY

2.0 For the purpose of this standard, the following definitions shall apply.

2.1 Interchangeable Type Syringes — Those syringes whose barrels and pistons for one size are mutually interchangeable.

3. SHAPE, SIZES AND DIMENSIONS

3.1 Typical shape of all-glass, interchangeable hypodermic syringe is shown in Fig. 1.

3.2 The capacities, scale intervals, and other critical dimensions of the syringes shall be in accordance with Fig. 1 and Table 1.

3.3 The inside diameter of the barrel and the outside diameter of the piston for the syringes shall be in accordance with Table 2.

*Dimensions of hypodemic syringes, interchangeable type.

†General requirements for syringes of medical use (*first revision*).

‡Rules for rounding off numerical values (*revised*).

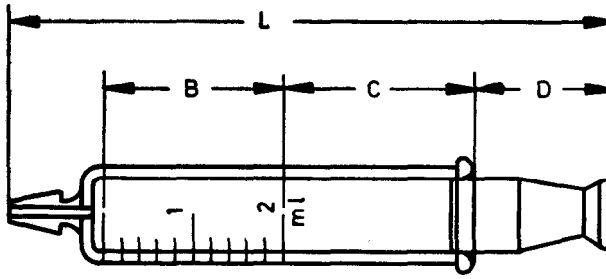

FIG. 1 HYPODERMIC SYRINGES, INTERCHANGEABLE TYPE FOR GENERAL PURPOSE

4. REQUIREMENTS

4.1 The male conical tip of the nozzle shall be of Luer or Luer lock type and shall comply with IS :3234-1979*. The tip shall be ground. The Luer lock shall be in accordance with Fig. 2 of IS :3236-1980† till the publication of the second revision of IS :3234-1979*.

4.2 **Numbering** — The numbering of scale intervals shall be inaccordance with col 5 of Table 1. The number shall be close to, but shall not touch the ends of the graduation mark to which it relates. The numbering shall generally conform to the details given in Fig. 2. The numbers and graduations shall be clearly defined, indelible and easily legible.

4.3 The piston shall be easily visible through the barrel and the fiducial line sball be capable of being judged against the graduations very accurately.

4.4 Diameter of effluent shall be in accordance with col 9 of Table 1. It shall be concentric with the tip.

5. TESTS

5.1 The interchangeable type hypodermic syringes shall pass all tests specified under 8 of IS : 3235-1980‡.

*Specification for conical fitting for hypodermic syringes, needles and other medical equipment, Luer type (first revision).

†Specification for hypodermic syringes for general purposes *(first revision)*.

‡General requirements for syringes for medical use *(first revision)*.

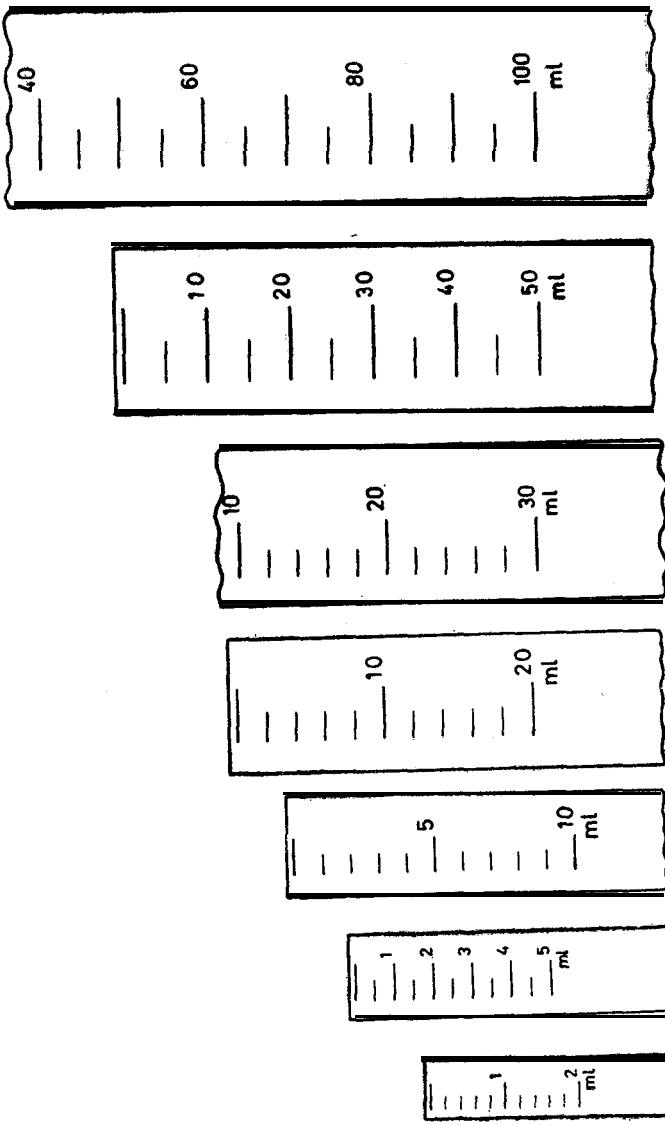

FIG. 2 GRADUATIONS ON ALL-GLASS HYPODERMIC SYRINGES

TABLE 1 THE SIZES, GRADUATED SCALE AND DIMENSIONS FOR ALL-GLASS INTERCHANGEABLE TYPE, HYPODERMIC SYRINGES

(Clauses 3.2 and 4.2 ; and *Fig.*)

Graduated Capacity of Syringe	Length of Graduated Scale *B*	Scale Interval*	Minimum Length of Long Graduation Marks†	Numbering of Scale Intervals	Length of Non-Graduated Part of the Barrel of the Syringe *C*	Minimum Length of Projection of Piston *D*	Minimum Thickness of Glass	Diameter of Effluent	Maximum Overall Length of Syringe *L*
(1) ml	(2) Percent	(3) mm	(4) mm	(5)	(6) mm	(7) mm	(8) mm	(9) mm	(10) mm
2	31 ± 0·5	0·2	6	1, 2	*25* to *30*	12	1'2	0·8 to 1.8	90
5	41 ± 0·5	0·5	8	1, 2, 3, 4, 5	*30* to *35*	13	1·4	0·8 to 1·8	100
10	57 ± 0·5	1	10	5, 10	to *3 5*	15	1·4	1·0 to 2·1	125
20	63 ± 1·0	2	13	0, 20	*35* to *40*	15	1·6	1·0 to 2·1	140
30	75 ± 1·0	2	13	0, 20, 30	*40* to *45*	17	1·6	1·0 to 2·1	155
50	82 ± 1·0	5	16	0, 20, 30, 40, 50	*40* to *45*	20	1·8	1.6 to 2·1	170
100	105 ± 1·0	5	18	0, 40, *60, 80,* 00	*45* to *50*	20	1·8	1·6 to 2.1	190

*Finer graduations are permitted

†Short graduation shall be equal to half the length of long graduations,

TABLE 2 DIAMETERS OF BARREL AND PISTONS OF INTERCHANGEABLE TYPE SYRINGES
(*Clause* 3.3)

GRADUATED CAPACITY OF SYRINGE	BARREL DIAMETER		PISTON DIAMETER	
	Minimum	Maximum	Minimum	Maximum
(1)	(2)	(3)	(4)	(5)
	mm	mm	mm	mm
2	9.143	9.145	9·138	9·140
5	12.445	12.447	12.440	12.442
10	14.985	14.987	14980	14.982
20	20.065	20·067	20·059	20.061
30	22.567	22.569	22.560	22.562
50	27·939	27·941	27.930	27.932
100	34·822	34·824	34817	34.819

6. MARKING

6.1 Each syringe shall be legibly and indelibly marked on its barrel with the following:

a) Manufacturer's name, initials or recognized trade-mark;

b) The capacity and its unit in ml; and

c) The word 'interchangeable'in capital letters.

6.1.1 Syringes may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, *testing* and quality control which is devised and supervised by ISI and operated by the producer. IS1 marked products are also continuously checked by ISI or conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the IS1 Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

7. PACKING

7.1 The syringes may be packed as agreed to between the manufacturer and the purchaser.

8. SAMPLING

8.1 Sampling scheme and criteria for acceptance shall be as agreed to between the manufacturer and the purchaser. However, a recommended sampling plan is given in Appendix A.

APPENDIX A
(*Clause* 8.1)

SAMPLING PLAN AND CRITERIA FORJCONFORMITY

A-l. LOT

A-l.1 In any consignment, all the syringes produced from the same material of the same type, shape and dimension under similar conditions shall constitute a lot.

A-l.2 The number of syringes to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and **2** of Table 3.

TABLE 3 SCALE OF SAMPLING

LOT SIZ (1)	SAMPLE SIZE (2)	SUB-SAMPL E SIZE (3)
Up to 100	5	5
101 to 150	8	5
151 to 500	13	8
501 to 1 000	20	13
1 001 to 10 000	32	13
10 001 and above	50	20

A-1.2.1 These syringes shall be selected from the lot at random and in order to ensure the randomness of selection, procedure given in IS : 4905-1968* may be followed.

A-2. NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

A-2.1 All the syringes selected at random in accordance with col 1 and 2 of Table 3 shall be tested for dimensions, capacity, shock test, leakage test, test for entraped fluid, interchangeability test and freedom from straie and strain. A syringe shall be considered as defective if it fails to meet any one or more of these requirements. A lot shall be considered as conforming to these requirements if none of the syringes in the sample is found to be defective in any of these tests.

A-2.2 If the lot is found to be conforming to the requirements given in A-2.1, the test for corrosion, permanency of marking, dry heat test and alkalinity test shall be carried out on the sub-samples selected according to col 3 of Table 3. A lot shall be considered as conforming to these requirements if none of the syringes in the sub-sample fails to meet any of these requirements.

A-2.3 The lot shall be considered as conforming to the standard if **A-2.1** and A-2.2 are satisfied.

*Methods for random sampling.

(*Continued from page 2*)

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